

TOPCARE ACID REDUCER- famotidine tablet, film coated
Topco Associates LLC

Topco Associates LLC. Acid Reducer Drug Facts

Active ingredient (in each tablet)

Famotidine 10 mg

Purpose

Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating, or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- adults and children 12 years and over:
- to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
- to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
- do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture

Inactive ingredients

carnauba wax, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, pregelatinized starch, polydextrose, polyethylene glycol, talc, titanium dioxide, triacetin

Questions or comments?

1-888-423-0139

Principal Display Panel

COMPARE TO PEPCID® AC ACTIVE INGREDIENT

SEE NEW WARNINGS

ORIGINAL STRENGTH

Acid Reducer

FAMOTIDINE TABLETS, 10 mg

ACID REDUCER

OUR PHARMACISTS RECOMMEND

Just One Tablet

Prevents & Relieves Heartburn Due to Acid Indigestion

90 TABLETS

actual size



TOPCARE ACID REDUCER

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-141	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)		FAMOTIDINE	10 mg	
Inactive Ingredients				
Ingredient Name			Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIACETIN (UNII: XHX3C3X673)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
Product Characteristics				
Color	PINK	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	L141	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-141-72	1 in 1 CARTON	09/11/2009	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-141-65	30 in 1 CARTON	10/13/2009	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:36800-141-75	1 in 1 CARTON	03/22/2021	
3		90 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing		Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA075400	09/11/2009	

Labeler - Topco Associates LLC (006935977)

Revised: 3/2021

Topco Associates LLC